

***In re National Prescription Opiate Litigation: MDL 2804***

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE  
OPINIONS AND PROPOSED TESTIMONY OF JAMES RAFALSKI  
AND CRAIG MCCANN**

**Summary Sheet of Concise Issues Raised**

**Motion Names:** Defendants' Motion to Exclude the Opinions and Proposed Testimony of James Rafalski (Dkt # 1785-1)

Defendants' Motion to Exclude the Opinion and Proposed Testimony of Craig McCann (Dkt # 1783-1)<sup>1</sup>

**Concise Description of Issues:**

Defendants' motions to exclude the opinions and testimony of Mr. Rafalski and Dr. McCann should be denied for the following reasons.

1. Mr. Rafalski has adequately disclosed the bases for his opinions. Defendants assert that Mr. Rafalski is basing his opinion on undisclosed "legal guidance" from the DEA. This is incorrect. Mr. Rafalski's 186-page report sets forth in detail the basis for his opinions: publicly available statutory and regulatory materials, along with a review of the evidence in this case, and his extensive professional experience. The Sixth Circuit has repeatedly found the experience of DEA agents on the job sufficient basis for them to offer their opinions. *See e.g., United States v. Ham*, 628 F.3d 801 (6<sup>th</sup> Cir. 2011); *United States v. Lopez-Medina*, 461 F.3d 724 (6<sup>th</sup> Cir. 2006). Here, Mr. Rafalski is relying on his 39 years of law enforcement experience—including 13 years as a DEA diversion investigator—where he applied the DEA's regulatory regime to the SOM programs of registrants. This is exactly what he does in his expert report when he analyzes Defendants SOM programs, including by reviewing the internal documents produced by Defendants.

2. The methodologies Mr. Rafalski offers are reliable. Mr. Rafalski identifies five potential methodologies for screening suspicious orders for unusual size. One of these methodologies—the *Masters* methodology—was confirmed by the D.C. Circuit. Variations of the remaining methodologies *have been used by several of the Defendants themselves* at various times. Mr. Rafalski also assumes that if a Defendant fails to perform due diligence on a suspicious order, all subsequent orders by the registrant must be held, regardless of whether those orders would have been independently flagged by a suspicious order methodology. Defendants complain that this assumption has never been "used in the real world," but ignore that this common-sense assumption was validated by the DEA as well as by some of the Defendants. Defendants' arguments at any rate go to weight not admissibility, and, thus, are not proper Daubert grounds for exclusion.

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<sup>1</sup> Because of the overlapping arguments raised in these motions, Plaintiffs are filing a single opposition brief and summary sheet addressing both motions.

3. There is no reason for Mr. Rafalski to review suspicious orders in order to support his opinions. Defendants repeatedly criticize Mr. Rafalski for failing to review and opine on specific suspicious orders. This type of review is not necessary. The opinion Mr. Rafalski is offering is that Defendants were obligated to investigate all suspicious orders, including those identified by Dr. McCann's analysis, prior to shipping them and failed to do so. Given this, Mr. Rafalski had no reason to determine whether these orders were in fact diverted after being shipped. When asked by defense counsel to express a view as to whether orders that should not have been shipped were necessarily diverted, Mr. Rafalski responded that the fact that an order was flagged as suspicious made it more probable than not that diversion could occur. Defendants cannot bootstrap testimony they elicited, and then distorted, to create a basis for excluding an opinion Mr. Rafalski has not given.

4. The fact that Defendants could have used an alternative to Plaintiffs' methodologies does not mean that these methodologies are unreliable. As explained above, all of these methodologies are a reliable means of identifying suspicious orders of unusual size, and Defendants offer no basis, other than sheer speculation, that another reliable method would have actually identified a significantly different set of orders.

5. The argument that Dr. McCann's analysis does not reflect any legal duties owed by Defendants is premised on an unreasonably narrow reading of the CSA and its applicable regulations. In both motions, Defendants essentially argue that unless a requirement is specifically enumerated in a regulation, it does not exist. This ignores that Defendants are broadly required to maintain effective controls against diversion under the CSA. In order to maintain such effective controls, a Defendant must design and operate a system to identify suspicious orders, report to DEA suspicious orders, and decline to ship a suspicious order unless, through due diligence, the Defendant can determine that the order is not likely to be diverted. Mr. Rafalski's report sets forth his opinion as to how Defendants breached these duties. Dr. McCann's analysis provides an estimate of the suspicious orders that Defendants would have identified had they employed a reliable methodology. Taken together, Mr. Rafalski's and Dr. McCann's expert reports establish that Defendants breached their legal duties, provide an estimate as to the magnitude of this breach, and are part of Plaintiffs' overall framework of causation and damages.

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